



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,288	11/13/2001	Frans Gerrit Davelaar	AHP-98249	5326
25291	7590	05/16/2005	EXAMINER	
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			FOLEY, SHANON A	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,288

Applicant(s)

DAVELAAR, FRANS GERRIT

Examiner

Shanon Foley

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

pd

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-15, 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Poston et al. (WO 99/53950) for reasons of record.

Applicant states that Poston et al. require the addition of interferon because it is a crucial element that cannot be omitted from the *in ovo* vaccine without a significant adverse effect.

Applicant also cites MPEP § 2144.04, which states that an omission of an element while retaining the element's function is unobvious.

The passage and the case law cited by applicant is absolutely correct. However, the discussion presented in MPEP § 2144.04 is applicable to "obvious" reasoning and is not relevant to the instant anticipatory rejection. In any case, the instant specification and claims do not exclude any particular ingredient since "consisting essentially of" is interpreted as "comprising" in the instant case. Neither the specification nor the claims indicate that an element, thought to be essential in the prior art, is now excluded by the instant teaching. The omission of a specific element from "consisting essentially of" is not apparent merely in the absence of discussion. A person of skill reading the instant claims would not conclude that interferon is specifically excluded from the open claim language presented.

Art Unit: 1648

Applicant also discusses transitional claim language and states that a composition “consisting essentially of” specified elements distinguishes over a composition that require at least one additional ingredient. Applicant states that the instant specification shows efficacy, despite the inclusion of interferon while Poston et al. require co-administration of interferon in every instance. Applicant stresses that there is no discussion of the addition of interferon in the instant disclosure. Applicant reasons that this lack of teaching excludes interferon from the instant composition.

Applicant’s arguments have been fully considered, but are found unpersuasive. The claims are drawn to a composition and a method of protecting an avian host by administering a composition “consisting essentially of” a TRT virus *in ovo*. There is no discussion provided in the specification or the claims concerning what elements are intended to be excluded by the transitional phrase. There is no evidence presented in the disclosure that the inclusion of interferon would affect the basic and novel characteristics of the instant composition. Therefore, “consisting essentially of” is interpreted as “comprising” any ingredient in addition to the recited elements. Applicant is correct that there is no teaching regarding the inclusion of interferon. However, there is also no discussion provided for the exclusion of interferon, or any other element. Therefore, the specification is silent with respect to defining over the inclusion or exclusion of any particular element. A person of skill in the art would not conclude that any particular element is excluded from the claims merely from the lack of discussion of that element in the specification. If interferon is intended to be excluded without some mention of it in the original disclosure, it cannot be predicted which other elements are also intended to be excluded since they have not been discussed in the specification or in the prosecution of the case. For

Art Unit: 1648

example, instant claims 16 and 17 list other avian vaccines that are to be co-administered with TRT. Does the absence of recitation or discussion exclude other viral vaccines? From applicant's arguments, it would appear that absence specifically excludes anything not mentioned. However, this reasoning is in direct contradiction to the open claim language which "comprises" anything not mentioned in addition to the ingredients that are mentioned. For these reasons, it is determined that the exclusion of any particular element, i.e., interferon, is not supported by the instant disclosure or claims.

Claim Rejections - 35 USC § 102

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Poston et al., *supra* for reasons of record.

Applicant traverses the rejection for the same reasons presented above. Specifically, applicant argues that interferon is absent from the instant claims and that this absence expressly excludes interferon. Applicant also discusses the efficacy obtained with the instant composition without the inclusion of interferon, which is a crucial ingredient taught by Poston et al.

Applicant's arguments have been fully considered, but are found unpersuasive. The mere absence of discussion or recitation of an ingredient does not specifically exclude it from the

Art Unit: 1648

claims. The claims recite open claim language, which includes the addition of any ingredient, whether or not recited and discussed.

Claims 2 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poston et al. as applied to claims 1, 3-9, 15, 17 and 18 above, and further in view of Ricks et al. (Advances in Veterinary Medicine. 1999; 41: 495-515, provided in the IDS) for reasons of record.

Applicant states that an omission of an element with the retention of an elements function is unobvious. Applicant argues that neither Poston et al. nor Ricks et al. teach safe vaccination without the inclusion of interferon.

Applicant's arguments have been fully considered, but are found unpersuasive. The instant claims and teachings in the disclosure do not exclude any particular element or ingredient. The absence of discussion does not exclude any specific ingredient from the open claim language recited. In view of this open claim language, it is determined that there is no difference between the teachings of Poston et al. and the instant claims, i.e. no surprising result.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

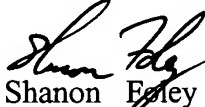
Art Unit: 1648

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-Th 6:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shanon Foley
Primary Examiner
Art Unit 1648